Packaging and Labeling Submissions to the NVSL

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The packaging and labeling of biological substances for shipment requires familiarity with current rules and regulations, which frequently change. Shippers are responsible for proper packaging, marking and labeling, documentation, classification, and identification of each shipment. **Failure to follow regulations can result in substantial financial penalties.**

Applicable Regulations

Anyone sending material to the NVSL should be in compliance with all applicable regulations. Regulations governing packaging and labeling of interstate shipments of etiologic agents are found in:

- Title 9 Code of Federal Regulations (CFR), Parts 121 and 122: These USDA regulations cover (1) the transfer of select agents/toxins and (2) the permits needed to ship organisms and vectors.
- Title 49 CFR Part 173: These U.S. Department of Transportation regulations contain general requirements for shipments and packaging.
    - 49 CFR 173.134 defines infectious substances and related terms.

    - 49 CFR 173.217 has additional requirements for shipments containing solid carbon dioxide (dry ice).
- Airline shipments also should be in compliance with current International Air Transport Association (IATA) regulations for dangerous goods.

Definitions

All specimens or reagents sent to the NVSL (Ames or Plum Island) are biological substances. These include, but are not restricted to, excreta, secreta, blood, serum, tissues, organs, animals or animal parts, tissue cultures, and viruses or other microorganisms (either infectious or inactivated).

Biological materials that are known to contain, or could contain, etiologic agents are divided into two groups:

1. **Biological Substance, Category A:** Materials known to contain certain **etiologic agents** (i.e., an infectious substance transported in a form which, when exposure occurs, is capable of causing permanent disability or a life-threatening or fatal disease to humans or animals)
2. **Biological Substance, Category B:** Excreta, secreta, blood and its components, tissue, tissue fluids, etc., which the shipper *reasonably believes* may contain an etiologic agent and that is being shipped for purposes of diagnosis (i.e., a diagnostic specimen) or investigation.

General Recommendations

- For routine serological testing, submit one tube containing 2 milliliters (ml) of clear serum per animal for each test requested. (Disease investigation cases may require additional volume.) Label each tube with the Sample ID, exactly as indicated in Block 21 in Form VS 10-4.
    - If virus detection is required from serologic specimens, contact the appropriate laboratory for volume requirements.
- Pack fresh and formalin-fixed specimens separately. Ship in separate containers when possible.
- Double bag all fresh tissues.
- Formalin-fixed specimens: Specimens may be shipped in a plastic specimen jar containing a 10:1 (liquid to tissue) volume of formalin. Do **not** use bags (Whirlpacks, zipper-closure, or heat-sealed) in lieu of a jar. Alternatively,

adequately fixed specimens may be removed from formalin, wrapped with formalin saturated gauze or paper towels, and then placed in a leak-proof plastic bag. Submission forms should be protected by placing in separate sealed bag.
- Cool with ice packs if the sample will reach the NVSL within 24 hours. Use "foam" ice, picnic packs, or sealed frozen containers of ice. Never use cubed or crushed ice, even if it is enclosed in a plastic bag.
- If tissues or swabs are to be in transit more than 48 hours, package with dry ice, unless the samples should not be frozen. When using dry ice, tightly seal all containers; CO_2 gas can inactivate some viruses and prohibit diagnostic isolation. Do not freeze dry ice or use dry ice in boxes that contain formalin-fixed tissues. Dry ice is considered a dangerous good; packages with dry ice must meet Category A Biological Substance shipping requirements, and not all carriers will accept packages containing dry ice.

Packaging and Labeling Submissions

Packaging kits are available upon request from the NVSL. These kits contain instructions, labels, an acceptable secondary vessel, and a shipping box meeting drop-test requirements. Contact the NVSL Shipping Department at 515-337-6614 for more information.

The following information is intended as a general guideline only. Shippers should read official rules and regulations for detailed information.

Category B Biological Substances (most diagnostic specimens)

- Packaged according to regulations in 49 CFR 173.199
- Place samples in a sealed primary container. Maximum volume per primary container is 1 liter (L).
- Wrap the primary container in sufficient dry absorbent material (for example, cotton) to absorb liquid contents in case of breakage. Do not use sawdust or vermiculite. Absorbent material is not required for solid shipments unless there is a risk of residual liquid.
- Place the primary container in a secondary container. The primary or secondary container must be able to withstand a 95 kPa pressure test.

- Place the secondary container in a certified outer box that will pass a 1.2-meter drop test. The maximum liquid volume allowed per box is 4 L. Solids must not exceed 4 kilograms (or 8 pounds) per box.
- Include an itemized list of contents between the secondary container and the outer box.
- Label the box properly. Mark the proper shipping name (Biological Substance, Category B) in letters at least 5 millimeters high adjacent to a "UN3373" mark or label. Add the name, address, and telephone number of the shipper **and** the consignee.
- Add the NVSL Priority Designation to the shipping box and the submission form.
- Samples preserved in formaldehyde are exempt from Category B regulations *provided that* the concentration of formaldehyde does not exceed 10 percent.

Category A Biological Substances (known etiological agents)

- Packaged in accordance with regulations in 49 CFR 173.196 .
- Category A samples must be packaged to withstand leakage of contents, shocks, pressure changes, and other conditions in ordinary transportation handling.
- Individuals shipping Category A items must be certified shippers, formally trained in handling Dangerous Goods. Certification is needed to sign the "Declaration of Dangerous Goods" form.
- Follow the procedures for Category B, with the following additional procedures:
    - The primary container must be watertight and sealed with waterproof tape. The primary container must contain a label identifying the contents.
    - Each primary container must be separately wrapped with packing material.
    - The name, address, and telephone number of the shipper must be on the secondary container.
    - The outer box requires an Infectious Substance label. The UN number is UN2814 or UN2900, depending on known medical history, symptoms of the source (human or animal), endemic local conditions, and professional judgment.
    - Interstate movement of Category A substances requires a US Veterinary Permit for the Importation and Transportation of Controlled Material and Organisms and Vectors. The permit is provided by the **recipient** of the shipment.

        - To submit Category A substances to the NVSL, a copy of the necessary permit must be enclosed in the shipment.
        - Individuals wishing to receive Category A substances from the NVSL must apply for a permit from the National Center for Import and Export.
        - Place one copy of the permit in the shipping box, outside the secondary container. Affix five additional copies to the outside of the shipping box.
    - Affix a signed Declaration of Dangerous Goods form to the outer box.
- Packages containing dry ice are handled as Category A shipments. Place dry ice between the secondary container and outer shipping container. Add a Dry Ice (medical use only) label to the outer box.
- Shipments over 50 ml or 50 grams must be sent by cargo aircraft only.

Related Resources

- Brochure: Transporting Infectious Substances Safely (U.S. Department of Transportation)

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